4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 74

[Docket No. FDA-2016-F-0821]

Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-)] Copper; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of December 2, 2016, for the final rule that appeared in the Federal Register of November 1, 2016, and that amended the color additive regulations to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for intraocular lenses (IOLs). We are taking this action to ensure clarity that the effective date in the final rule remains December 2, 2016.

DATES: Effective date of final rule published in the Federal Register of November 1, 2016 (81 FR 75689), confirmed: December 2, 2016.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 240-402-1275.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 1, 2016 (81 FR 75689), we amended the color additive regulations in § 73.3126 (21 CFR 73.3126) and

§ 74.3045 (21 CFR 74.3045) to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for IOLs.

The preamble to the final rule stated that persons who would be adversely affected by one or more provisions in the final rule could file electronic or written objections (81 FR 75689 at 75691). We also stated that the effective date of the final rule would be on December 2, 2016, unless a person properly files an objection or request for a hearing to review any provisions in the final rule (81 FR 75689). We explained that, to file an objection, a person must, among other things, specify with particularity the provision(s) of the regulation to which they object and the grounds for the objection (81 FR 75689 at 75691). Within each objection, a person also must specifically state whether he/she requests a hearing. We received no objections or requests for a hearing on the final rule that met these requirements. We received five general comments, including one that disagreed with the rule, but the comments did not meet the requirements to be considered an objection under 21 CFR 12.22(a)(3). Therefore, we find that the effective date of the final rule that published in the Federal Register of November 1, 2016, should be confirmed.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, we are giving notice that no objections or requests for a hearing were filed in response to

the November 1, 2016, final rule. Accordingly, the amendments issued thereby became effective December 2, 2016.

Dated: January 9, 2017.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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